

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | | |
|---|---|---------------------------|
| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION |) | MDL NO. 1203 |
| _____ |) | |
| THIS DOCUMENT RELATES TO: |) | |
| SHEILA BROWN, et al. |) | |
| v. |) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION |) | 2:16 MD 1203 |

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9052

Bartle, J.

April 30, 2013

Kim L. Schepp ("Ms. Schepp" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2012, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam U. Ansari, M.D., F.A.H.A. Based on an echocardiogram dated March 28, 2011, Dr. Ansari attested in Part II of Ms. Schepp's Green Form that claimant suffered from mild aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.³ Based on

2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Ansari also attested that claimant suffered from mild mitral regurgitation and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$859,612.⁴

Dr. Ansari also attested in claimant's Green Form that Ms. Schepp did not suffer from aortic stenosis. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)e). As the Trust does not contest Ms. Schepp's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In February, 2012, the Trust forwarded the claim for review by Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for Dr. Ansari's finding that claimant did not have aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation. In support of this conclusion, Dr. Bier stated:

The aortic valve is clearly stenotic. The Doppler data required to quantitate the severity is not included on the disc. The following day, 3/29/11, the patient underwent catheterization to clarify the severity of the aortic stenosis and the valve area was

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

found to be 0.9 sq. cm (severe). On 3/30/11 the patient underwent aortic valve replacement for severe aortic stenosis. It is no [sic] reasonable to claim there is no significant aortic stenosis given the totality of the information.⁵

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that Ms. Schepp was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that she was entitled to Matrix A-1 level benefits because Dr. Bier used a "totality of information" standard for determining the presence of aortic stenosis rather than the Continuity Equation, the method required by the Settlement Agreement. Claimant also submitted a statement from

5. As part of his audit, Dr. Bier also reviewed a November 14, 2002 echocardiogram that claimant submitted with a Gray Form in December, 2002. The Gray Form is the form under the Settlement Agreement used to report the results of an echocardiogram that is relied upon by a claimant to establish her eligibility for Matrix Benefits. See Settlement Agreement § VI.C.2.e.-f. In reviewing this echocardiogram, Dr. Bier agreed that there was a reasonable medical basis for finding that claimant did not have aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation. In the Attestation of Auditing Cardiologist, Dr. Bier stated, in relevant part, "There is no significant stenosis on the study from 1/14/02[.]"

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schepp's claim.

her attesting physician. Dr. Ansari concluded, in relevant part, that:

Dr. Bier and the Trust created an unwarranted conflict by substituting the hydraulic equation at cardiac catheterization [sic] to calculate [aortic valve area]. The Trust adopted a modality and methodology that is precluded and not permitted according to the terms of the Settlement Agreement and the Green Form, *supra*. The [aortic valve area] measurement of $< 1.0 \text{ cm}^2$, which was measured by hydraulic equation in the U of M cardiac catheterization [sic] laboratory, is not the mandated methodology or modality established in the terms of the Settlement Agreement or the Green Form, and it is inadmissible according to the Court approved Settlement Agreement, the Official Notice of Final Judicial Approval of the Settlement Agreement, and the Green Form. The correct modality and methodology for determining [aortic valve area] is calculation of [aortic valve area] by Continuity Equation by [two dimensional transthoracic echocardiogram] and Doppler as shown in the *qualifying* [two dimensional transthoracic echocardiogram] of November 14, 2202 [sic] and the *attestation* [two dimensional transthoracic echocardiogram] of March 28, 2011. In Ms. Schepp's medical records, there are four [aortic valve area] measurement[s] that are $> 1.0 \text{ cm}^2$ that meet the mandates and are shown in both the *qualifying* and the *attestation* [two dimensional transthoracic echocardiograms] and Dopplers, *supra*.

(footnote omitted).

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Bier submitted a declaration in which he confirmed his previous conclusion that there was no reasonable medical basis for Dr. Ansari's finding that claimant did not have aortic stenosis. Specifically, Dr. Bier stated, in relevant part:

10. Based on my review, I confirm my finding at audit, that there is no reasonable medical basis for the Attesting Physician's representation that Claimant did not have Aortic Stenosis. At Contest, I reviewed the March 28, 2011 echocardiogram, which included Doppler tracings. I agree that this echo does not show severe Aortic Stenosis (i.e., Aortic Stenosis with an aortic valve area $< 1\text{cm}^2$). However, taking into consideration all of the medical records and documentation submitted in support of the Claim, it is apparent that Claimant had severe Aortic Stenosis at the time of her March 31, 2011 surgery and there is no reasonable medical basis to conclude otherwise.
11. The following medical records and documentation informed my conclusion that Claimant had Aortic Stenosis with an aortic valve area $< 1\text{cm}^2$:
12. Claimant's [transesophageal echocardiogram] of 3/1/11 was interpreted as showing severe [aortic stenosis] (< 1.0). See March 1, 2011 [transesophageal echocardiogram] Report ("The aortic valve... was found to have an aortic valve area of 0.7 via 2D and 0.83 cm^2 on the 3-dimensional.")
13. While Claimant's March 1, 2011 Cardiac Catheterization report indicates aortic valve areas of 1.0cm^2 and 1.5cm^2 , it is noted on the report that these measurements are unreliable. See March 1, 2011 [transesophageal echocardiogram] Report ("Probable severe aortic stenosis as patient's cardiac output was likely over estimated by the thermal dilution method ...")
14. Two days after the March 28, 2011 Echocardiogram of Attestation, on March 30, 2011, Claimant underwent a Cardiac Catheterization which shows severe Aortic Stenosis.

15. Claimant's March 31, 2011 surgery was performed for severe, symptomatic aortic Stenosis, as noted in the History & Physical and the Operative Report. See March 28, 2011 Consultation ("... diagnosed with severe aortic stenosis,") and March 31, 2011 Operative Report.
16. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that Claimant did not have Aortic Stenosis.

The Trust then issued a final post-audit determination, again determining that Ms. Schepp was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Schepp's claim should be paid. On November 8, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8959 (Nov. 8, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 19, 2013, and claimant submitted a sur-reply on March 6, 2013. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Schepp did not have aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant reasserts the arguments that she made during contest. In response, the Trust argues that the claim properly was reduced to the B-1 Matrix because, "given the totality of the claim," Ms. Schepp had severe aortic stenosis prior to her aortic valve replacement surgery. In her sur-reply, claimant argues that the Trust's definition of aortic stenosis and use of a "totality of information" standard to determine the presence of aortic stenosis is contrary to the terms of the Settlement Agreement.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her attesting physician's representation that Ms. Schepp did not have aortic stenosis. In connection with the audit of Ms. Schepp's

claim, the Trust's auditing cardiologist reviewed claimant's echocardiograms dated November 14, 2002 and March 28, 2011.⁷ In both instances, the auditing cardiologist concluded that claimant did not have aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation.

As to claimant's March 28, 2011 echocardiogram, the Trust's auditing cardiologist stated, "I agree that this [echocardiogram] does not show severe Aortic Stenosis (i.e. Aortic Stenosis with an aortic valve area $< 1\text{cm}^2$).\" As to claimant's November 14, 2012 echocardiogram, Dr. Bier concluded that there was a reasonable medical basis for finding that claimant did not have an aortic valve area < 1.0 square centimeter.

The Trust argues that an auditing cardiologist may determine that a representation by an attesting physician that a claimant has aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation is without a reasonable medical basis by reference to aortic valve area calculations made using methods other than the Continuity Equation and medical records documenting "aortic stenosis," even when the auditing cardiologist has reviewed that claimant's

7. The auditing cardiologist also reviewed claimant's February 14, 2007 echocardiogram, but he did not make a finding as to aortic stenosis. The report for this echocardiogram, however, states that the echocardiogram demonstrated an "aortic valve area of 1.4.\" Notably, the Trust does not dispute the opinion of the attesting physician that this calculation was performed using the Continuity Equation.

echocardiograms and determined that they do not demonstrate aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation. We disagree.

In PTO No. 9009 (Feb. 26, 2013), we rejected a similar argument raised by the Trust. As we stated, "We reject the Trust's assertion that it may find the presence of aortic stenosis from the 'totality' of claimant's medical evidence rather than based on a measurement of claimant's aortic valve area by the Continuity Equation." Id. at 8. In reaching this conclusion, we relied on our earlier decision in PTO No. 8562 (Nov. 15, 2010), where we rejected a similar argument raised by a claimant who sought to negate a finding of aortic stenosis by relying on evidence other than a measurement of his aortic valve area by the Continuity Equation. Id. at 12 n.11. There, we stated, "We reject claimant's argument that he may disprove the existence of aortic stenosis by a method other than the Continuity Equation, which is specifically required by the Settlement Agreement." (citing Settlement Agreement § IV.B.2.d.(2)(c)i)e)).

We must apply the Settlement Agreement as written. As the Trust concedes that claimant's echocardiograms do not demonstrate aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation, the Settlement

Agreement mandates that the present claim cannot be reduced to Matrix B-1.⁸

For the foregoing reasons, we conclude that claimant has met her burden of proving that she does not have aortic stenosis with an aortic valve area of < 1.0 square centimeter by the Continuity Equation. Therefore, we will reverse the Trust's denial of Ms. Schepp's claim for Matrix A-1, Level III benefits.

8. As the Trust notes, the auditing cardiologist's conclusion of severe aortic stenosis was based on a March 1, 2011 transesophageal echocardiogram, March 1, 2011 and March 28, 2011 cardiac catheterizations, and a History & Physical and Operative Report relating to claimant's aortic valve surgery. The Trust does not contend that any of these records reflects a finding of aortic stenosis < 1.0 square centimeter by the Continuity Equation. The Trust also does not dispute the opinion of the attesting physician that any aortic valve area measurements identified on these reports were not determined by the Continuity Equation. Thus, the Trust's reliance on these records is misplaced.